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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,656	02/03/2004	Craig P. Smith	USAV20010002USDIV	1668

5487 7590 09/14/2004

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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/770,656	Applicant(s) SMITH ET AL.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 28 and 29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

1. Claims 28-29 are pending.
2. Claims 28-29 are rejected.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

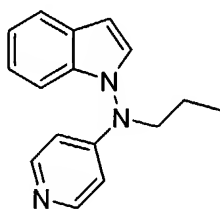
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1614

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang, L. et al. in view of Eglen et al. and in further view of Eglen, R. M. et al. and in still further view of Stedman's MEDICAL DICTIONARY. The prior art reference of Tang, L. et al. teach of the known compound of besipirdine, which has the following chemical structure:



In addition, Tang, L. et al. teach that besipirdine is known to inhibit voltage-dependent sodium and potassium channels (see abstract). Tang, L. et al. also teach that besipirdine is a structural analogue of 4-aminopyridine, and like 4-aminopyridine, besipirdine inhibits outward voltage-dependent currents, (see 2nd column, page 2471). Accordingly, this teaching regarding the structural similarity between besipirdine and 4-aminopyridine provides the skilled artisan with motivation to use structurally similar and analogous compounds to treat ailments where voltage-dependent ion channels may be treated by their inhibition. Tang, L. et al. also disclose that besipirdine is known in the art to have the pharmacological properties of having an effect on particularly the cholinergic system, (see column 1, page 2468). Tang, L. et al. also teach that it is known to treat

Art Unit: 1614

other diseases with modulators of voltage-dependent sodium channels, (see 2nd column, page 2471). Effland et al. of U.S. Patent No. 5,519,131 teaches compounds of formula (Ia), (see columns 1 and 2). Effland et al. teach that the compounds of formula (I) are useful in the treatment of ailments that are characterized by a decreased cholinergic or adrenergic function. Effland et al. also teach that this utility is manifested by the ability of these compounds to inhibit the enzyme acetylcholinesterase (AChE) and thereby increase levels of acetylcholine. Effland et al. also disclose that it is generally accepted that the physiological role of AChE is the rapid hydrolysis and inactivation of acetylcholine. Inhibitors of AChE show marked cholinomimetic effects in cholinergically-innervated effector organs and have been used in a various ailments where there is decreased amounts of choline, (see from column 4, line 46 to column 5, line 12). Next, the prior art reference of Eglen, R. M. et al. teach that it is known in the art that selective muscarinic receptor ligands have therapeutic efficacy on smooth muscle disorders, namely urinary urge incontinence due to bladder smooth muscle hyperactivity, (see 1st column, page 429). The instant specification defines bladder irritation with the conditions of interstitial cystitis and over-active bladder, (see page 11 of the instant specification). Stedman's MEDICAL DICTIONARY, 25th Edition, defines the term cystitis as inflammation of a bladder, especially the urinary bladder and further defines interstitial cystitis as a chronic inflammatory condition of unknown etiology involving the mucosa and muscularis of the bladder, resulting in *reduced* bladder capacity, pain relieved by voiding, and severe bladder *irritative* symptoms, (see 2nd column, page 391) [emphasis added]. Accordingly, the definitions of Stedman's

Art Unit: 1614

MEDICAL DICTIONARY, 25th Edition provide one having ordinary skill in the art with the motivation to treat inter alia irritation of the bladder with the employ the pyridinyl indole-containing compounds of Effland et al. as well as besipirdine of Tang. L.

7. Due to the fact that L.Tang et al. establish that besipirdine inhibit voltage-dependent sodium and potassium channels and the cholinergic system and that Effland et al. teach that the pyridinyl indole-containing compounds affect the levels of acetylcholine, it would logically follow for the skilled artisan to treat other ailments, namely urinary incontinence, where cholinergic systems and levels are altered, as taught by Eglen, R. M. et al. Clearly, it would have been obvious to one having ordinary skill in the art to employ the pyridinyl indole-containing compounds of Effland et al. as well as besipirdine for the treating ailments, such as urinary incontinence, where the levels of choline are altered, as discussed in the prior art reference of Eglen, R. M. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (703) 872-9306.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair->

Art Unit: 1614

direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 1-866-217-9197 (toll free).


DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
September 12, 2004